

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS FO Box 1430 Alexandria, Virginia 22313-1450 www.tepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,261	04/10/2006	Kenya Shitara	Q105979	9631
65565 7590 05/26/2009 SUGHRUE-265550 2100 PENNSYLVANIA AVE., NW			EXAMINER	
			DAHLE, CHUN WU	
WASHINGTO	WASHINGTON, DC 20037-3213		ART UNIT	PAPER NUMBER
			1644	
			MAIL DATE	DELIVERY MODE
			05/26/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/575,261 SHITARA ET AL Office Action Summary Examiner Art Unit CHUN DAHLE 1644 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 03 March 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-39 is/are pending in the application. 4a) Of the above claim(s) 21-35, 38, 39 is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) \_\_\_\_\_ is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-20.36 and 37 are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s)/Mail Date. Notice of Draftsperson's Patent Drawing Review (PTO-948)

Imformation Disclosure Statement(s) (PTC/G5/08)
Paper No(s)/Mail Date \_\_\_\_\_\_.

Notice of Informal Patent Application

6) Other:

Application/Control Number: 10/575,261 Page 2

Art Unit: 1644

## DETAILED ACTION

1. Applicant's election without traverse of Group I (drawn to a fusion protein), filed on

March 3, 2009, is acknowledged.

Claims 1-39 are pending.

Claims 21-35, 38 and 39 have been withdrawn from further consideration pursuant to 37

CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or

linking claim.

Claims 1-20 and 36-37 are currently under consideration.

2. Upon further consideration, the following species election has been set forth herein. The

Examiner apologizes for any inconvenience regarding this matter.

Election/Restrictions

3. This application contains claims directed to more than one species of the generic

invention. These species are deemed to lack unity of invention because they are not so linked as

to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to elect one specific fusion protein composition wherein the fusion

protein comprises specific binding protein, wherein the binding protein is:

A) an antibody,

B) a soluble receptor, OR

C) a ligand protein.

Application/Control Number: 10/575,261

Art Unit: 1644

If (B) is elected, applicant is further required to elect specific soluble receptor and to provide either name (e.g. a soluble TNF receptor II as recited in claim 14) or SEQ ID NO (e.g. SEQ ID NO:64 as recited in claim 15).

If (C) is elected, applicant is further required to elect specific ligand protein and to provide either name (LFA-3 as recited in claim 17) or SEQ ID NO (e.g. SEQ ID NO:65 as recited in claim 18).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: claims 1-6, 36, and 37.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

Shinkawa et al. (JBC January 2003. 278;5:3466-3473, reference on IDS) teach antibodies that are produced in host cells that have deficiency in fucosyltransferase (e.g. see Abstract).

Application/Control Number: 10/575,261

Art Unit: 1644

Such antibodies have N-glycan structure without fucose; thus, fucose is not bound to Nacetylglucosamine in the reducing end in the sugar chains (e.g. see Table 1 on page 3469).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

- 4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun Dahle whose telephone number is 571-272-8142. The examiner can normally be reached on 8:30-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Ram Shukla can be reached 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1644

/Chun Dahle/

Examiner, Art Unit 1644